

California Business and Professions Code 1206.5

Creates additional restrictions on personnel who may perform CLIA-regulated testing

Waived Personnel

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Section 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A person licensed under Chapter 6.5 (commencing with Section 2840).
- (8) A perfusionist if authorized by and performed in compliance with Section 2590.
- (9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
- (11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.
- (12) Other health care personnel providing direct patient care.

HSC 120917 designates HIV counselors trained by the California Office of AIDS and operating in OA funded sites as "other health care personnel" authorized by this statute to perform CLIA-waived HIV testing.

Moderate Complexity Personnel

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A perfusionist if authorized by and performed in compliance with Section 2590.
- (8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
- (10) Any person if performing blood gas analysis in compliance with Section 1245.
- (11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2, or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
- (12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052.